DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership to serve on the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Council). ACBSCT shall advise the Secretary of HHS (Secretary), through the HRSA Administrator, on the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program (Program).

AUTHORITY: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109-129). The Council is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

DATE: Written nominations for membership on ACBSCT will be received continuously.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary,

ACBSCT, Healthcare Systems Bureau, HRSA, Room 08W60, 5600 Fishers Lane,

Rockville, Maryland 20857, or sent via email to: ACBSCTHRSA@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Shelley Grant, Executive Secretary,

ACBSCT, at (301) 443-8036 or email sgrant@hrsa.gov. A copy of the ACBSCT charter

and a list of current members may be obtained by accessing the ACBSCT website at https://bloodcell.transplant.hrsa.gov/about/advisory council/index.html.

SUPPLEMENTARY INFORMATION: ACBSCT was established pursuant to Public Law 109-129 as amended by Public Law 111-264; 42 U.S.C. 274k; Section 379 of the Public Health Service Act. In accordance with Public Law 92-463, the ACBSCT was chartered on December 19, 2006. ACBSCT meets up to three times during the fiscal year.

ACBSCT shall, as requested by the Secretary, discuss and make recommendations regarding the Program. It shall provide a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation. ACBSCT shall advise, assist, consult, and make recommendations, at the request of the Secretary, on (1) broad Program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory, (2) requirements regarding informed consent for cord blood donation, (3) accreditation requirements for cord blood banks, (4) the scientific factors that define a cord blood unit as high quality, (5) public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices, (6) criteria for selecting the appropriate blood stem source for transplantation, (7) program priorities; (8) research priorities, and (9) the scope and design of the Stem Cell Therapeutic Outcomes Database. At the request of the Secretary, ACBSCT shall also review and advise on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy pertaining to the compatibility of international regulations, and actions that may be taken by state and federal governments and public and private insurers to increase donation and access to transplantation. ACBSCT shall also make recommendations regarding research

on emerging therapies using cells from bone marrow and cord blood. The Council may meet up to three times during the fiscal year.

NOMINATIONS: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACBSCT. The Council shall consist of up to 25 members who are SGEs and 6 ex-officio, non-voting members. The Secretary appoints ACBSCT SGEs with the expertise needed to fulfill the duties of the Council. HRSA is seeking nominees who are outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of bone marrow transplants; recipients of cord blood transplants; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists, hematology, and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public to serve as members. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to ACBSCT will be invited to serve for a term of 2 years, and are eligible to serve as many as 3 consecutive 2-year terms. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACBSCT meetings and/or conducting other business on behalf of ACBSCT, as authorized by 5 U.S.C. § 5703 of the FACA for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (i.e., what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACBSCT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee; (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that the membership of ACBSCT is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a conflict between the SGE's public duties as a member of ACBSCT and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Maria G. Button,

Director, Executive Secretariat.

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